Medication Guide
Sitagliptin and Metformin Hydrochloride
Sit-a-glip-tin-met-FOR-min
Tablets, for oral use

Read this Medication Guide carefully before you start taking sitagliptin and metformin hydrochloride tablets and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about sitagliptin and metformin hydrochloride tablets, ask your doctor or pharmacist.

What is the most important information I should know about sitagliptin and metformin hydrochloride tablets?

Sitagliptin and metformin hydrochloride tablets can cause serious side effects, including:

1. **Lactic Acidosis. Metformin, one of the medicines in sitagliptin and metformin hydrochloride tablets, can cause a rare but serious condition called lactic acidosis (a buildup of an acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in the hospital.**

Stop taking sitagliptin and metformin hydrochloride tablets and call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heartbeat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel sleepy or drowsy
- you have stomach pains, nausea or vomiting

Most people who have had lactic acidosis with metformin have other things that, combined with the metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance for getting lactic acidosis with sitagliptin and metformin hydrochloride tablets if you:

- have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye
- have liver problems
- drink alcohol very often, or drink a lot of alcohol in short-term "binge" drinking
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids.
- have surgery
- have a heart attack, severe infection, or stroke
- are 65 years of age or older
- have a genetically inherited disease affecting mitochondria (the energy-producing parts within cells) such as mitochondrial encephalomyopathy with lactic acidosis, and stroke-like episodes (MELAS) syndrome and maternally inherited diabetes and deafness (MIDD).

The best way to keep from having a problem with lactic acidosis from metformin is to tell your doctor if you have any of the problems in the list above. Your doctor may decide to stop your Sitagliptin and metformin hydrochloride tablets for a while if you have any of these things. Sitagliptin and metformin hydrochloride tablets can have other serious side effects. See "**What are the possible side effects of sitagliptin and metformin hydrochloride tablets?**"

2. **Pancreatitis** (inflammation of the pancreas) which may be severe and lead to death. Certain medical problems make you more likely to get pancreatitis.

   Before you start taking sitagliptin and metformin hydrochloride tablets, tell your doctor if you have ever had:
   - Pancreatitis
   - stones in your gallbladder (gallstones)
   - a history of alcoholism
   - high blood triglyceride levels

Stop taking sitagliptin and metformin hydrochloride tablets and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

3. Heart failure. Heart failure means that your heart does not pump blood well enough.

Before you start taking sitagliptin and metformin hydrochloride tablets, tell your doctor if you have ever had heart failure or have problems with your kidneys. Contact your doctor right away if you have any of the following symptoms:

- increasing shortness of breath or trouble breathing, especially when you lie down
- swelling or fluid retention, especially in the feet, ankles or legs
- an unusually fast increase in weight
- unusual tiredness

These may be symptoms of heart failure.

What are sitagliptin and metformin hydrochloride tablets?

- Sitagliptin and metformin hydrochloride tablets are a prescription medicine that contains 2 prescription diabetes medicines, sitagliptin (JANUVIA) and metformin. Sitagliptin and metformin hydrochloride tablets can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- Sitagliptin and metformin hydrochloride tablets are not for people with type 1 diabetes.
- If you have had pancreatitis (inflammation of the pancreas) in the past, it is not known if you have a higher chance of getting pancreatitis while you take sitagliptin and metformin hydrochloride tablets.
- The safety and effectiveness of sitagliptin and metformin hydrochloride tablets have not been established in pediatric patients.

Who should not take sitagliptin and metformin hydrochloride tablets?

Do not take sitagliptin and metformin hydrochloride tablets if you:

- have severe kidney problems.
- have diabetic ketoacidosis.
- are allergic to any of the ingredients in sitagliptin and metformin hydrochloride tablets. See the end of this Medication Guide for a complete list of ingredients in sitagliptin and metformin hydrochloride tablets.

Symptoms of a serious allergic reaction to sitagliptin and metformin hydrochloride tablets may include rash, raised red patches on your skin (hives) or swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing.

What should I tell my doctor before taking sitagliptin and metformin hydrochloride tablets?

Before you take sitagliptin and metformin hydrochloride tablets, tell your doctor about all of your medical conditions, including if you:

- have or have had inflammation of your pancreas (pancreatitis).
- have kidney problems.
- have liver problems.
- have heart failure.
- drink alcohol very often or drink a lot of alcohol in short-term "binge" drinking.
- are going to get an injection of dye or contrast agents for an x-ray procedure. Sitagliptin and metformin hydrochloride tablets may need to be stopped for a short time. Talk to your doctor about when you should stop sitagliptin and metformin hydrochloride tablets and when you should start sitagliptin and metformin hydrochloride tablets again. See "**What is the most important information I should know about sitagliptin and metformin hydrochloride tablets?**".
- have low levels of vitamin B_{12} in your blood.
- are pregnant or plan to become pregnant. It is not known if sitagliptin and metformin hydrochloride tablets will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if sitagliptin and metformin hydrochloride tablets will pass into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking sitagliptin and metformin hydrochloride tablets.
- are a woman who has not gone through menopause (premenopausal) who does not have periods regularly or at all. Sitagliptin and metformin hydrochloride tablets can cause the release of an egg from an ovary in a woman (ovulation). This can increase your chance of getting pregnant. Tell your doctor right away if you become pregnant while taking sitagliptin and metformin hydrochloride tablets.
- have a genetically inherited disease affecting mitochondria (the energy-producing parts within cells) such as MELAS syndrome and MIDD.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Sitagliptin and metformin hydrochloride tablets may affect the way other medicines work and other medicines may affect how sitagliptin and metformin hydrochloride tablets works.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

How should I take sitagliptin and metformin hydrochloride tablets?

- Take sitagliptin and metformin hydrochloride tablets exactly as your doctor tells you. Your doctor will tell you how many sitagliptin and metformin hydrochloride tablets to take and when you should take them.
- Your doctor may change your dose of sitagliptin and

metformin hydrochloride tablets if needed.

- Your doctor may tell you to take sitagliptin and metformin hydrochloride tablets along with certain other diabetes medicines. Low blood sugar (hypoglycemia) can happen more often when sitagliptin and metformin hydrochloride tablets are taken with certain other diabetes medicines. See "**What are the possible side effects of sitagliptin and metformin hydrochloride tablets?**".
- Take sitagliptin and metformin hydrochloride tablets with meals to help to lower your chance of having an upset stomach.
- Do not break or cut sitagliptin and metformin hydrochloride tablets before swallowing. If you cannot swallow sitagliptin and metformin hydrochloride tablets whole, tell your doctor.
- Continue to take sitagliptin and metformin hydrochloride tablets as long as your doctor tells you.
- If you take too much sitagliptin and metformin hydrochloride tablets, call your doctor or local Poison Control Center right away.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take 2 doses of sitagliptin and metformin hydrochloride tablets at the same time.
- You may need to stop taking sitagliptin and metformin hydrochloride tablets for a short time. Call your doctor for instructions if you:
  - are dehydrated (have lost too much body fluid). Dehydration can occur if you are sick with severe vomiting, diarrhea or fever, or if you drink a lot less fluid than normal.
  - plan to have surgery.
  - are going to get an injection of dye or contrast agent for an x-ray procedure. See "**What is the most important information I should know about sitagliptin and metformin hydrochloride tablets?**" and "**What should I tell my doctor before taking sitagliptin and metformin hydrochloride tablets?**".
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these problems and follow your doctor's instructions.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking sitagliptin and metformin hydrochloride tablets.
- Talk to your doctor about how to prevent, recognize and manage low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and problems you have because of your diabetes.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with sitagliptin and metformin hydrochloride tablets.

What are the possible side effects of sitagliptin and metformin hydrochloride tablets?

Sitagliptin and metformin hydrochloride tablets may cause serious side effects, including:

- See "**What is the most important information I should know about sitagliptin and metformin hydrochloride tablets?**".
- **Kidney problems,** sometimes requiring dialysis.
- **Low vitamin B_{12} (vitamin B_{12} deficiency).** Using metformin for long periods of time may cause a decrease in the amount of vitamin B_{12} in your blood, especially if you have had low vitamin B_{12} blood levels before. Your doctor may do blood tests to check your vitamin B_{12} levels.
- **Low blood sugar (hypoglycemia).** If you take sitagliptin and metformin hydrochloride tablets with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you use sitagliptin and metformin hydrochloride tablets. Signs and symptoms of low blood sugar may include:
  - headache
  - irritability
  - dizziness
  - drowsiness
  - hunger
  - confusion
  - sweating
  - feeling jittery
  - weakness
  - fast heart beat
- **Serious allergic reactions.** If you have any symptoms of a serious allergic reaction, stop taking sitagliptin and metformin hydrochloride tablets and call your doctor right away or get emergency medical help. See "**Who should not take sitagliptin and metformin hydrochloride tablets?**". Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.
- **Joint pain.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in sitagliptin and metformin hydrochloride tablets, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.
- **Skin reaction.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in sitagliptin and metformin hydrochloride tablets, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your doctor right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your doctor may tell you to stop taking sitagliptin and metformin hydrochloride tablets.

The most common side effects of sitagliptin and metformin hydrochloride tablets include:

- stuffy or runny nose and sore throat
- upper respiratory infection
- low blood sugar (hypoglycemia) when used in combination with certain medicines, such as a sulfonylurea or insulin
- gas, upset stomach, indigestion
- weakness
- nausea and vomiting
- headache
- diarrhea

Taking sitagliptin and metformin hydrochloride tablets with meals can help lessen the common stomach side effects of metformin that usually happen at the beginning of treatment. If you have unusual or sudden stomach problems, talk with your doctor. Stomach problems that start later during treatment may be a sign of something more serious.

Sitagliptin and metformin hydrochloride tablets may have other side effects, including swelling of the hands or legs. Swelling of the hands and legs can happen if you take sitagliptin and metformin hydrochloride tablets in combination with rosiglitazone (Avandia). Rosiglitazone is another type of diabetes medicine.

Tell your doctor if you have any side effect that bothers you, or does not go away.

These are not all the possible side effects of sitagliptin and metformin hydrochloride tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store sitagliptin and metformin hydrochloride tablets?

Store sitagliptin and metformin hydrochloride tablets at room temperature, between 68°F to 77°F (20°C to 25°C).

Keep sitagliptin and metformin hydrochloride tablets and all medicines out of the reach of children.

General information about the safe and effective use of sitagliptin and metformin hydrochloride tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use sitagliptin and metformin hydrochloride tablets for a condition for which it was not prescribed. Do not give sitagliptin and metformin hydrochloride tablets to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about sitagliptin and metformin hydrochloride tablets. If you would like to know more information, talk with your doctor. You can ask your doctor or pharmacist for information about sitagliptin and metformin hydrochloride tablets that is written for health professionals.

What are the ingredients in sitagliptin and metformin hydrochloride tablets?

Active ingredients: sitagliptin phosphate monohydrate USP and metformin hydrochloride USP.

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, dicalcium phosphate anhydrous, magnesium stearate, microcrystalline cellulose, povidone, sodium lauryl sulfate. In addition, the film coating contains the following inactive ingredients: black iron oxide, polyvinyl alcohol-part hydrolyzed, polyethylene glycol 3350, iron oxide yellow, iron oxide red, talc and titanium dioxide.

For more information, call Laurus Generics Inc. at 1-833-3- LAURUS (1-833-352-8787).

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Revised: 8/2026

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